K091286
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510(k) Summary
Prepared April 27, 2009

Sponsor: Siemens Medical Solutions, Inc.,
Ultrasound Division
1230 Shorebird Way
Mountain View, California 94043

MAY 15 2009

Contact Person: Shelly Pearce
Telephone: (650) 694-5988
Fax: (650) 694-5580

Submission Date: April 27, 2009

Device Name: syngo US Workplace

Common Name: System, Image Processing, Radiological

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Picture Archiving and Communications System FR # 892.2050 Product Code 90-LLZ

A. Legally Marketed Predicate Devices

syngo US Workplace, K060992, K072090; syngo AHP, K083149.

B. Device Description:

The modified software feature provides for the measurement of anatomical structures and for analysis packages that provide information.

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C. Intended Use

Syngo US Workplace is used to view post processed ultrasound images, to store and print images, and to manipulate and make measurements on images using a personal computer or a compatible DICOM compliant PACS system.

The Siemens ultrasound imaging systems are intended for the following applications: General Radiology, Fetal, Abdominal, Intraoperative, Pediatric, Small Parts, Neonatal/Adult Cephalic, Cardiac, Transesophageal, Pelvic, Transcranial, OB/GYN, Urology, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The systems also provide for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The Arterial Health Package (AHP) software provides the physician with the capability to measure Intima Media Thickness and the option to reference normative tables that have been validated and published in peer-reviewed studies. The information is intended to provide the physician with an easily understood tool for communicating with patients regarding state of their cardiovascular system. This feature should be utilized according to the "ASE Consensus Statement; Use of Carotid Ultrasound to Identify Subclinical Vascular Disease and Evaluate Cardiovascular Disease Risk: A Consensus Statement from the American Association of Echocardiography; Carotid Intima-Media Thickness Task Force, Endorsed by the Society for Vascular Imaging".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2009

Siemens Medical Solutions USA, Inc.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K091286
Trade/Device Name: Syngo US Workplace
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Product Code: LLZ
Dated: April 30, 2009
Received: May 1, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

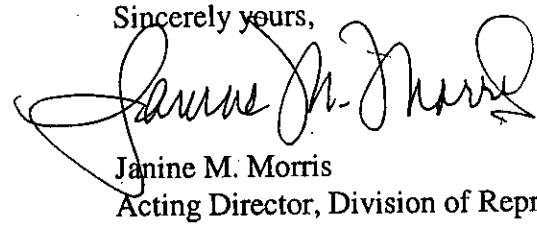
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use

510(k) Number (if known): K091286

Device Name: Syngo US Workplace

Indications for Use:

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Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091286